NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AZTRAZENECA AB, *et al.* Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD, *et al.*, Defendants.	Civil Action No. 05-5553 (JAP) (consolidated case) **OPINION**

PISANO, District Judge.

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca, LP, KBI Inc., KBI-E Inc. (together "Astra" or "Plaintiff") bring this Hatch-Waxman patent infringement action against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (together "DRL" or "Defendant"). Astra manufactures and markets Nexium, a drug product containing the active ingredient esomeprazole magnesium, which is a proton-pump inhibitor, and holds several patents covering various aspects of the esomeprazole magnesium product, the esomeprazole magnesium active ingredient, and the process for making both. Such patents include those at issue here: U.S Patent Nos. 5,714,504 (the '504 patent), 5,877,192 (the '192 patent) and 6,369,085 (the '085 patent).

According to the complaint, DRL submitted abbreviated new drug application ("ANDA") No. 78-279 seeking to manufacture "Esomeprazole Magnesium Delayed Release Capsules" containing the active ingredient esomeprazole magnesium. DRL indicated that it intends to market the ANDA product prior to the expiration of the '504 and '872 patents. This action followed.

Presently before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on March 24, 2010. This Opinion addresses the proper construction of the disputed claim terms.

I. Standards for Claim Construction

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc*., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370 (1996), therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d 1312 (internal

quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)).

In the process of determining the meaning of a claim as understood by a person of ordinary skill in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314. While a court is permitted to turn to extrinsic evidence, such evidence is generally of

less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

II. The Disputed Claim Terms

The parties have identified a number of disputed claim terms in each patent. The Court will address each of these in turn.

A. Disputed Claim Terms in the '872 Patent

1. "optical purity"

This disputed term is found in claims 1, 2, 4, 5, 7, 8, 10, and 11 of the '872 patent. Plaintiff asserts that this phrase means "a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer."[1] DRL argues that this term

[1]The parties were unable to provide the Court with a joint claim construction chart and each submitted their own summary of the terms in dispute along with the proposed constructions of the parties. For the purposes of this decision, the parties' proposed constructions are taken from the chart accompanying Plaintiff's letter to the Court of February 3, 2010, to which counsel for Astra referred the Court (without objection) as the final summary of the claim terms that are in dispute. Tr. at 19-20.

should be construed as meaning "essentially free of R-omeprazole." The key difference between the two constructions boils down to basic grammar; Astra's proposed construction recognizes that the word "purity" in the disputed term is a noun while DRL's proposed construction seems more suited for an adjective. Indeed, the term is clearly used as a noun in the specification and claims of the '872 patent. For example, the specification refers to "high optical purity" or "very high optical purity" a number of times. *See*, *e.g.*, '872 patent, col. 1, line 15 ("The present invention is directed to new compounds of high optical purity..."); col 3, lines 49-50 ("they can be obtained in very high optical purity"). Claim 1 refers to "an optical purity of at least about 94% enantiomeric excess." Similarly, claim 2 similar refers to an "optical purity" of "at least 94% enantiomeric excess."

Furthermore, Astra's proposed construction is based upon the plain meaning of the claim language. *See Phillips*, 415 F.3d at 1314 (claim language is first source for claim construction). As Astra points out, each time "optical purity" appears in a claim it is used in conjunction with a percentage range of enantiomeric excess. The Court, therefore, shall adopt Plaintiff's proposed construction, and construe the term "optical purity" to mean "a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer."

2. "in crystalline form"

This term is found in claims 3, 6, 9 and 12. Plaintiff offers the following proposed construction: "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species." DRL on the

other hand, argues that this phrase means "a solid in which the constituent molecules are arranged in an orderly, repeating pattern or lattice in all three spatial dimensions." DRL Brf. at 18. The primary difference between the two proffered constructions is the degree of crystallinity required by each. While Plaintiff's construction would require the magnesium salt of esomeprazole to exhibit only "some" degree of crystallinity, DRL's construction requires the compound to be entirely crystalline.

While Astra argues that nothing in the claim language suggests a 100% crystalline requirement, DRL similarly argues that nothing in the claim language suggests a limitation of "some." Indeed, the plain language of the claims do not require a specific degree of crystallinity. The Court therefore, first looks to the intrinsic evidence to discern the meaning of a claim as understood by a person of ordinary skill in the art.

In support of its construction, Astra points to Example 6 in the specification, which describes the preparation of an optically pure magnesium salt of the (-)-enantiomer of omeprazole, '872 patent, col. 8, lines 17-52, and is noted to be the preferred embodiment of this invention, *id.*, col. 9, lines 28-29. It is clear that the material described in Example 6 is crystalline, as it states that "the optical purity (e.e.) has been enhanced from 80% to 98.4% simply by crystallizing the Mg-salt from a mixture of acetone and methanol. The product was crystalline as shown by powder X-ray diffraction...". '872 patent, col. 8, lines 46-49. While the specification does not state the degree of crystallinity the material, contemporaneous notes from the inventor show the product of Example 6 to have a crystallinity of 49%. Pl. Exs. '872-5 and '505-11. The product of Example 6, therefore,

supports Astra's construction, which does not require the material to be entirely crystalline.

Extrinsic evidence supports Astra's construction as well. For example, Plaintiff's expert, Dr. Davies, explained that it is rare for a material be have a degree of crystallinity of 100% and that a person of ordinary skill in the art generally understands that a reference to "crystalline" material does not require that the material be completely or even mostly crystalline. Davies Decl. ¶¶ 72, 73. Consequently, the Court shall construe the phrase "in crystalline form" to mean "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species."

3. "at least about 98.4% enantiomeric excess"

This term is found in claim 4, which reads: "Magnesium salt of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2- pyridinyl)methyl]sulfinyl]-1H-benzimidazole in an optical purity of *at least about 98.4% enantiomeric excess*." '872 patent, col. 14, lines 24-27 (emphasis supplied). Astra asserts that the entire disputed phrase should be construed to mean "at least 98% enantiomeric excess." DRL argues that the term "at least about" should be construed to mean "equal to or more than approximately." Unlike Astra, DRL's construction assigns no specific numerical value to the level of purity described.

The Court finds DRL's construction to be more consistent with the ordinary and customary meaning of the term. The issue being only briefly addressed in the voluminous submissions of the parties, Astra simply provides no adequate justification for assigning a numerical limit of 98% to this claim term. Therefore, the Court shall construe the term "at least about" in this phrase as "equal to or more than approximately."

4. "at least 98.4% enantiomeric excess"

This term is found in claim 5. Claim 5 adopts the same language as claim 4 except the word "about" has been removed from the claim. Under the proposed construction by Astra, the purity described by this phrase in claim 5 "must not be less than 98.4% enantiomeric excess." DRL, on the other hand, contends that the term "at least" means "equal to or more than." Because the Court finds that there is no ambiguity as to the meaning of the phrase "at least 98.4% enantiomeric excess" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '872 patent. The ordinary and customary meaning of the term as understood by those of ordinary skill in the art shall apply.

5. "at least about 99.8% enantiomeric excess"

This term is found in claim 7. Astra asserts that the entire phrase should be construed to mean "at least 99% enantiomeric excess." DRL argues that the term "at least about" should be construed to mean "equal to or more than approximately." Claim 7 is identical to claim 4 except for the level of purity expressed. Consequently, for the same reasons as stated above with respect to claim 4, the Court finds DRL's construction to be more consistent with the plain language of the claim. Therefore, the Court adopts DRL's construction and shall construe the term "at least about" in this phrase as "equal to or more than approximately."

6. "at least 99.8% enantiomeric excess"

This term is found in claim 8. Under the proposed construction by Astra, the purity

described by this phrase "must not be less than 99.8% enantiomeric excess." DRL contends that the term "at least" means "equal to or more than." Because the Court finds that there is no ambiguity as to the meaning of the phrase "at least 99.8% enantiomeric excess" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '872 patent.

7. "at least about 99.9% enantiomeric excess"

This term is found in claim 10. Astra asserts that this phrase should be construed as "at least 99.9% enantiomeric excess." DRL contends that "at least about" means "equal to or more than approximately." Claim 10 is identical to claim 4 except for the level of purity expressed. Consequently, for the same reasons as stated with respect to claim 4, the Court finds that DRL's construction is more consistent with the plain language of the claim. Therefore, the Court adopts DRL's construction and shall construe the term "at least about" in this phrase as "equal to or more than approximately."

8. "at least 99.9% enantiomeric excess"

This term is found in claim 11. Under the proposed construction by Astra, the purity described by this phrase "must not be less than 99.9% enantiomeric excess." DRL contends that the term "at least" means "equal to or more than." Because the Court finds that there is no ambiguity as to the meaning of the phrase "at least 99.9% enantiomeric excess" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '872 patent.

B. Disputed Claim Terms in the '504 Patent

1. "pure"

This term is found in claims 1, 6 and 7. Plaintiff proposes the following construction: "essentially free from chemical impurities to permit use in a pharmaceutical formulation." Astra's construction goes on to state that "essentially free from chemical impurities to permit use in a pharmaceutical formulation" means 98% chemically pure. DRL contends that the disputed claim term should be construed as "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation."[2]

Both parties agree that the term "pure" as used in the aforementioned claims of the '504 patent limits the claims to a chemically pure alkaline salt of the (-)-enantiomer of omeprazole. The difference in the two constructions is that Astra's provides a quantitative limitation of 98% chemically pure, apparently derived from its proposed construction of the term "optically pure," which is discussed further below. However, such reliance is misplaced, as the disputed claim term "pure" relates to chemical purity, not optical purity. Indeed, Astra itself concedes that "pure" does not refer to optical purity. *See*, *e.g.*, Pl. Brf. at 5 (" 'pure' in claim 1 should mean something other than ... 'optically pure.' ") Moreover, where the term "essentially free" is used in the specification, the term is used to described optical purity, not chemical purity. '504 patent, col. 3, lines 31-35 ("With the expression

[2]This was the construction originally offered by Teva, one of the settling defendants in this case. In its letter to the Court of January 21, 2010, DRL stated that its claim construction briefing was coordinated with Teva and directed the Court to those portions of Teva's briefs relevant to DRL's arguments in support of its proposed constructions. The Court considered those materials in rendering this decision.

'optically pure Na+ salts of omeprazole" is meant the (+)-enantiomer of omeprazole Na-salt essentially free of the (-)-enantiomer and the (-)-enantiomer of omeprazole Na-salt essentially free of the (+)-enantiomer."). The testimony of Astra's expert, Dr. Davies, cited to by Astra in support of its construction (see Attachment 9 to Joint Statement), where Dr. Davies refers to levels of purity "98 percent and above," also is a reference to optical, and not chemical, purity. Astra simply has not established that there is any basis for reading the quantitative limitation of 98% into the disputed claim term. Without this limitation, the "essentially free" language proposed by Astra is ambiguous.

DRL's proposed construction, on the other hand, provides an unambiguous definition that would be understood by one of ordinary skill in the art. Plaintiff's expert, for example, states that "a skilled person would know that certain impurities ... are tolerated at only very low levels or not at all. In another instance the overall impurity level may be higher, if there is less risk associated with those particular impurities. Byrn Decl. at ¶ 42. Under DRL's proposed construction -- "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation" -- it would be clear whether a sample is one where, for example, "the overall impurity level may be higher." Consequently, the Court shall adopt DRL's proposed construction, and construe "pure" in the '504 patent to mean "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation."

2. "(-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole"

The parties dispute construction of this term which appears in claims 1, 6 and 7.

Plaintiff contends that this term, as used in the '504 patent, means "(-)-omeprazole of high optical purity, also referred to as (S)-omeprazole, the (S)-enantiomer of omeprazole." Astra further asserts that in the context of the '504 patent, "'high optical purity' means at least 94% enantiomeric excess (ee)." DRL construes the term as "the chemical name for esomeprazole or S-omeprazole." Therefore, the question with regard to the construction of this term is whether the construction should include an optical purity level and, consequently, exclude the prior-art racemic omeprazole.

The claims at issue expressly require the alkaline salts of the (-)-enantiomer of omeprazole. '504 patent, col. 14, lines 6-10. By focusing a person skilled in the art on the enantiomer, Astra asserts that the claims obviously require some level of optical purity. Indeed, a person of ordinary skill in the art would know that "[t]he '(-)' denotes that the compound has some level of optical purity." *Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 567 (D.N.J. 2009); *see also Ortho-McNeil Pharm., Inc. v. Myland Labs., Inc.*, 348 F.Supp.2d 713, 725-26, 729 (N.D.W.Va.2004) (where claim referred to "S(-)" enantiomer of levofloxacin but intrinsic record did not claim or identify a minimum level of optical purity, court construed claim to cover substantially optically pure levofloxacin and held that person skilled in the art would understand "S(-)" to require substantial optical purity). According to the specification, the invention of the '504 patent is directed to new compounds "of high optical purity." *Id.*, col. 1, lines 9-10. Consequently, "high optical purity" is the lower limit for optical purity of the invention.

The specification distinguishes between "high optical purity" and "very high optical

purity." '504 patent, col. 3, lines 43-47. With respect to "very high optical purity," the specification states as follows: "[b]ecause it is possible to purify optically impure or partially pure salts of the enantiomer of omeprazole by crystallization, they can be obtained in very high optical purity, namely ≥99.8% enantiomeric excess (ee.) ..." *Id.*, col. 3, lines 43-47. Accordingly, "very high optical purity"' is greater than or equal to 99.8% enantiomeric excess.

Turning to "high optical purity," the specification shows that the level of "high optical purity" achievable by methods in the '504 patent is no less than 94% enantiomeric excess. Example 12 describes the preparation of (-)-omeprazole which is used as an intermediate in several other examples for the preparation of the alkaline salts of (-)-omeprazole. '504 patent, col. 10, line 49 to col. 11, line 3. The optical purity of the (-)-omeprazole of example 12 is 94% enantiomeric excess before salt preparation. *Id.*, col. 10, line 67 to col. 11, line 2. Salt preparation enhances the optical purity of the starting material, so the optical purity of salts of the product of example 12 would be higher. (*See e.g.*, Examples 6 and 7). The (-)-omeprazole of example 12 illustrates the lowest levels that are covered by the invention. This example, therefore, illustrates the lower limit of the "high optical purity" of the invention. The claimed enantiomers of omeprazole and their salts must exhibit "high optical purity," meaning at least 94% enantiomeric access. Consequently, the Court shall construe the term "(-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" as found in the '504 patent in the manner proposed by Plaintiff.

3. "optically pure"

This term is found in claim 2. Plaintiff asserts that this term, as used in the '504 patent, means "essentially free of the (+)-enantiomer of omeprazole" and means "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)." DRL's proposed construction is as follows: "essentially free of R-omeprazole." The only difference between the two proffered constructions is that Plaintiff's further provides a clear, quantitative limit in that it specifies that "essentially free" means "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)."

The Court having construed the term "(-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" in claim 1 as meaning enantiomers of with an optical purity of least 94% enantiomeric excess, the doctrine of claim differentiation would require that the "optically pure" material in claim 2 exhibit an optical purity higher than that required by claim 1. *See Phillips*, 415 F.3d at 1315;. *RF Delaware. v. Pacific Keystone Techs.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003) (Under claim differentiation doctrine, the presence of a dependent claim adding a further limitation raises a presumption that the same limitation is not present in the independent claim.). Thus, Astra asserts that the "optically pure" alkaline salt of claim 2 must have an optical purity in excess of 94% enantiomeric excess.

In further support of this assertion, Astra points to the examples 1 and 2 in the specification. In each of those examples, the starting material is described as being

"contaminated" with 3% of the undesired enantiomer (94% enantiomeric excess). Astra argues that because "contaminated" material cannot properly be considered "optically pure," the term "optically pure" in claim 2 is being used to describe an optical purity greater than 94% ee.

Astra also notes that the alkaline salts of examples 1 through 7 have optical purities of at least 98% enantiomeric excess or higher. As such, the Court agrees with Plaintiff's assertion that the alkaline salts in these examples define the lower limit for the term "optically pure" as found in claim 2 of the '504 patent. Therefore, this term shall be construed as proposed by Plaintiff, namely to mean "essentially free of the (+)-enantiomer of omeprazole" and "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)."

4. "substantially crystalline form"

This phrase is found in claim 4. Plaintiff proposes the following construction of the terms in this phrase: "crystalline form" means "a compound having a repeating pattern of atoms or molecules of the constituent chemical species," and "substantially crystalline form" means "sufficient crystallinity present to permit further optical purification of the enantiomer if required." DRL asserts that the phrase "substantially crystalline form" means "almost entirely consisting of a solid in which the constituent molecules are arranged in an orderly, repeating pattern in all three special dimensions." Plaintiff's proposed definition of "crystalline form" is consistent with that of DRL. As DRL points out, "crystalline form" is a term that is widely understood by persons of ordinary skill in the art, and the definitions of

this term proposed by both parties are consistent with this understanding. *See*, *e.g.*, DRL Ex. 6, McGraw-Hill Dictionary of Scientific and Technical Terms at 390 (1984); Ex. 8, Hawley's Condensed Chemical Dictionary at 240 (1977).

The difference in the parties' construction centers on the term "substantially." DRL asserts that the term has no special meaning to one skilled in the art and, therefore, its ordinary, non-technical meaning should be applied. DRL's proposed construction, however, merely separates the terms in the phrase "substantially crystalline form" and defines each, with the resulting construction being the combination of those definitions. The proper question when making a claim construction determination is how the phrase would be understood by a person of ordinary skill in the art reading the patent. *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119-20 (Fed. Cir. 2002) (the term "substantially" may serve to describe the subject matter so that its scope would be understood by persons in the field of the invention and to distinguish the claimed subject matter from the prior art).

Astra asserts that the specification of the '504 patent identifies to persons skilled in the art when a material is in substantially crystalline form. The specification shows that crystallization may be used to purify optically impure or partially pure salts of omeprazole enantiomers to achieve optically pure compounds. '504 patent, col. 3, lines 43-47. The examples further show the optical purification. *See, e.g.*, examples 1 and 2, col. 6, line 36 to col. 7, line 10 (material purified from 94% ee to 99.8% ee); example 6, col. 8, lines 16-53 (material that is 49% crystalline purified from 80% ee to 98.4% ee); example 7, col. 8, line 54 to col. 9, line 30 (80% ee to approximately 99% ee). Consequently, a person skilled in

the art would understand from the specification that the meaning of "substantially crystalline form" is consistent with Astra's proposed construction. The Court, therefore, shall construe the phrase to mean "sufficient crystallinity present to permit further optical purification of the enantiomer if required."

5. "a pharmaceutical formulation"

This term is found in claims 1-7. Astra proposes the following construction: "a composition or mixture in a form suitable for administration to a patient for medical use, such as diagnosis, mitigation, or prevention of disease or disorders." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should apply. Alternatively, DRL proposes that the term be construed as "a medicament."

Astra's basis for its proposed construction of this term is not addressed anywhere in Astra's claim construction papers. Moreover, the Court discerns no ambiguity in the term and finds that its ordinary and customary meaning would be clear to one skilled in the art. Consequently, the Court agrees with DRL that no construction of this term is necessary. Rather, the plain meaning of the term as understood by someone of ordinary skill shall apply.

6. "solid state"

This term appears in claims 1-7 and 10. Astra asserts that this term means "a solid form rather than liquid, such as, a syrup or oil." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should

apply. Alternatively, DRL proposes that the term be construed as "a solid form."

With respect to its proposed construction, Astra provides no justification for the language that distinguishes a "solid form" from a "liquid, such as, a syrup or oil." Moreover, the Court agrees with DRL that no construction of this term is necessary finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

7. "therapeutically effective amount"

This term appears in claims 6 and 7. Astra contends that this term should be construed as "an amount sufficient to reduce the production of acid by the stomach." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should apply. Alternatively, DRL proposes that the term be construed as "an amount that causes a therapeutic effect."

Once again, support for its proposed construction of this term is found nowhere in Astra's claim construction papers, and the Court finds its construction to be somewhat inconsistent with the ordinary meaning of the term. The Court, therefore, accepts DRL's argument that this term need not be construed. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe "therapeutically effective amount." The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.

B. Disputed Claim Terms in the '192 Patent

1. "consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1Hbenzimidazole"

This phrase appears in claims 1 and 2 of the '192 patent. Plaintiff contends that this phrase means "(-)-omeprazole essentially free of (+)-omeprazole." Plaintiff further asserts that "essentially free of (+)-omeprazole" means at least 98% e.e." In essence, Astra is arguing that this phrase has the same meaning as the term "optically pure" as found in the '504 patent, which the Court construed to mean having a purity level of at least 98% ee.[3] DRL, on the other hand, argues that the proper construction of the phrase is "S-omeprazole [(-)-omeprazole] substantially free of R-omeprazole [(+)-omeprazole], in a free base form, that may also contain substances that do not materially affect the claimed novel properties of S-omeprazole [(-)-omeprazole]. DRL's construction does not specify a particular level of purity.

As Astra points out, the plain language of the claims show that (-)-omeprazole may be administered at two different levels of purity. The first is "consisting essentially of the (-)-enantiomer." '192 patent, claims 1 and 2. The second is "essentially devoid of its (+)-enantiomeric contaminant." *Id.*, claim 23. Thus, purity described in claims 1 and 2 is an optically-purified level relative to racemic omeprazole, but a less optically-purified level relative to the (-)-enantiomer of claim 23. *See Phillips*, 415 F.3d at 1315;. *RF Delaware*,

[3]The '192 patent states that it is an continuation-in-part of "Ser. No. 376,516, Jan. 23, 1995, Pat. No. 5,715,504." *See* '192 patent, "Related U.S. Application Data."

326 F.3d at 1263 (the presence of a dependent claim adding a further limitation raises a presumption that the same limitation is not present in the independent claim.).

The specification further describes the optical purity of the (-)-enantiomer in claims 1 and 2: "single enantiomer" means the (-)-enantiomer is "substantially free from its (+)-enantiomeric contaminant." '192 patent, col. 1, line 22-24. Therefore, the reference to(-)-omeprazole or "single enantiomer" is synonymous with the phrase "substantially free from its (+)-enantiomeric contaminant." Looking to the '504 patent, which is incorporated into the '192 patent, Astra argues that the phrase "consisting essentially of the (-)-enantiomer" means "optically pure." *See, e.g.*, '504 patent, col. 3, lines 31-35 ("With the expression 'optically pure Na+ sales of omeprazole' is meant ... the (-)-enantiomer essentially free of the (+)enantiomer.") As described *supra*, the Court has held that "optically pure" as used in the '504 patent means 98% ee.

During prosecution of the '192 patent, in response to a rejection by the examiner, the applicant deleted the phrase "substantially free of (+)-enantiomeric contaminant" and replaced it with "a proton pump inhibitor consisting essentially of." April 1, 1998 Office Action at 2; June 30, 1998 Amendment at 2. The rejection was then withdrawn and the examiner allowed the claims. July 24, 1998 Notice of Allowability. Clearly the examiner recognized that "consisting essentially of" was understood by a person skilled in the art. The Court, therefore, agrees with Plaintiff, that based upon the plain language of the claims, the specification and the file history, "consisting essentially of" means a (-)-enantiomer that is essentially free of its (+)-contaminant, which means at least 98% ee. Accordingly, the Court

shall construe the disputed term "consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5- dimethyl-2-pyridinyl)methyl]sulfinyl]-1-Hbenzimidazole" consistent with Plaintiff's proposed construction.

2. "so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases"

This phrase appears in claim 1 and claim 13 (absent "so as to effect"). Plaintiff and DRL differ in their approach to construction of the above terms/phrase and five others like it.[4] Plaintiff proposes separate constructions for certain discreet terms within the overall phrase. DRL, on the other hand, asserts that construction of this phrase (and the five others) is not required because it is not a limitation but rather the observed inherent result of the claimed method. However, to the extent construction would be required, DRL proposes a construction for the entirety of the phrase rather for each of the separate terms comprising the phrase.

The disputed phrase appears in its entirety in claim 1 as follows:

> A method for treatment of gastric acid related diseases by inhibition of gastric acid secretion comprising administering to a mammalian need of treatment a therapeutically effective amount of a proton pump inhibitor consisting

[4]There are six similar groups of claim terms at issue: "decreased interindividual variation in plasma levels (AUC)" (claims 1 and 13), "an increased average plasma level (AUC)" (claims 2 and 14), "less pronounced increase in gastrin levels in slow metabolisers during treatment of gastric acid related diseases" (claims 3 and 15), "a decreased CYP1A induction in slow metabolisers during treatment of gastric acid related diseases" (claims 4 and 16), "an improved antisecretory effect during the treatment of gastric acid related diseases" (claims 5 and 17), and "an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during the treatment of gastric related diseases" (claims 6 and 18).

> essentially of the consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl]sulfinyl]-1H-benzimidazole or a pharmaceutically acceptable salt thereof, *so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases*.

'192 patent, claim 1 (emphasis supplied).

Astra first proposes a construction with respect to the phrase "so as to effect," which Astra argues should be defined as "to bring about." Next, Astra proposes the following construction for "decreased interindividual variation in plasma levels (AUC)": "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." Last, Astra proposes that "treatment of gastric related diseases" be construed as "mitigating a symptom or effect of a condition associated with stomach acid."

DRL, on the other hand, contends that the phrase "so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases" is not a limitation but rather the observed inherent result of the claimed method. As such, DRL contends no construction is necessary. To the extent that construction is necessary, however, DRL asserts that this phrase means "an observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl]-1Hbenzimidazole that the average AUC differences among individuals treated with that compound are less than those differences among individuals treated with omeprazole, and that this distinction would support a claim

of superiority that the FDA would allow in advertising and product literature."

The threshold issue for the Court is whether the disputed claim term, and the five other similar claim terms (discussed below) requires construction at all. Citing *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."), DRL argues that the "so as to" and "wherein" clauses in the disputed phrase should be treated as the "whereby" clause in *Minton*, and be considered nonlimiting.

Astra, on the other hand, points out that "when the whereby clause states a condition that is material to patentability, it cannot be ignored to change the substance of the invention." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326 (Fed. Cir. 2005); *see also Fantasy Sports Properties, Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1111-16 (Fed. Cir. 2002); *Griffin v. Bertina*, 285 F.3d 1029, 1034, 62 U.S.P.Q.2d 1431 (Fed. Cir. 2002). In *Griffin*, for example, the court found that "wherein" clauses were claim limitations "because they relate back to and clarify what is required by the count. Each 'wherein' clause ... expresses the inventive discovery [and] ... elaborates the meaning of the preamble." *Griffin*, 285 F. 3d at 1033-34. Further, "the allegedly inherent properties of the 'wherein clauses' provide the necessary purpose to the steps. *Id.* Similarly, in the instant case, the disputed claim terms express the invention of the claimed compound at the high optical purity levels claimed. These are, for example, the unexpected and improved effects of administration of the claimed compound on individuals and the correlation between plasma levels (AUC), gastrin

levels or CYP1A induction and individuals referred to in the '192 patent as "slow metabolizers".

The Court agrees with Astra that, under the above standards, construction of these disputed terms is appropriate. Because DRL's proposed construction merely embodies its argument that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow ...," the Court rejects DRL's proposed construction.

Turning then to Astra's proposed construction for the phrase "so as to effect," which Astra alleges should be construed to mean "to bring about," the Court notes that Astra bases its proposed construction only the dictionary definition of the term "effect." *See* Pl. Ex. '192-2 at 4. Because there is no ambiguity as to the meaning of the phrase "so as to effect" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

Next, Astra proposes that "decreased interindividual variation in plasma levels (AUC)" should be construed to mean "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." Ample intrinsic evidence supports this construction and Astra's position that one of ordinary skill would understand the term "decreased" referred to a comparison with omeprazole. For example, the specification explains that omeprazole exhibits polymorphic metabolism,

meaning some individuals metabolize omeprazole slowly compared to the rest of the population, and these "slow metabolizers" will obtain higher than average plasma concentrations of the drug. '192 patent, col. 2, lines 16-21. Because "the inhibition of gastric acid secretion is correlated to the area under the plasma concentration versus time curve (AUC), a more pronounced effect from omeprazole is expected" in the slow metabolizers. *Id.*, col. 2, lines 22-25. The (-)-enantiomer of omeprazole is claimed in the '192 patent "as an improved alternative to omeprazole in the treatment gastric acid related diseases" because of "higher does efficiency" and "less interindividual variation in plasma levels (AUC)" between both slow and rapid metabolizers and within rapid metabolizers. *Id.*, col. 2, lines 28-36.

> Additionally, the specification of the '192 patent states that
>
> > the use of the (-)-enantiomer of omeprazole , or a pharmaceutically acceptable salt thereof, in the treatment of gastric acid related diseases as a mean to decrease interindividual variation in plasma levels compared to omeprazole is claimed. The use of the (-)-enantiomer of omeprazole to receive increased plasma levels (AUC) of the substance compared to those of racemic omeprazole and thereby a higher dose is also claimed.

'192 patent, col. 2, lines 38-46. *See also*, *id.*, col. 6, lines 27-34; col. 7, line 3-16. Consistent with the intrinsic evidence is certain extrinsic evidence pointed to by Astra, namely testimony of Dr. Tommy Andersson, who explained clinical studies showing decreased interindividual variation for esomeprazole as compared to omeprazole. Pl. Ex. '192-7 at 61-64.

The Court, therefore, construes the term "decreased interindividual variation in plasma levels (AUC)" should be construed to mean "a reduced difference or deviation in

blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve."

Last, Astra proposes that "treatment of gastric related diseases" be construed as "mitigating a symptom or effect of a condition associated with stomach acid." Because Astra identifies and the Court finds no ambiguity as to the meaning of the phrase "treatment of gastric related diseases" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

3. "increased average plasma levels (AUC)", "per dosage unit", "per unit dosage"

These terms are found in the phrases "an increased average plasma levels (AUC) per dosage unit" in claim 2 and "an increased average plasma level (AUC) per unit dosage" in claim 14 . Astra contends that the phrase "an increased average plasma levels (AUC)" should be construed to mean "greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve." Astra further proposes that "per dosage unit" or "per unit dosage" be construed as "for every specified quantity administered." DRL argues that construction of the phrases "an increased average plasma levels (AUC) per dosage unit" and "an increased average plasma level (AUC) per unit dosage" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is

required, DRL proposes the following construction: the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl] -1H-benzimidazole that the average AUC for individuals treated with that compound is greater than that for individuals treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For the same reasons expressed earlier, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this term is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

In support of its proposed construction of "an increased average plasma levels (AUC) per dosage unit", Astra points to various portions of the '192 patent specification:

> In rapid metabolisers the mean AUC at steady state (Day 7) of the (-)-enantiomer of omeprazole was almost 90% higher than that of omeprazole. This resulted in a more pronounced gastric acid antisecretory effect for the (-)-enantiomer of omeprazole compared to that of omeprazole. The inhibition of pentagastrin simulated gastric acid secretion was 62% for omeprazole and 79% for the (-)-enantiomer of omeprazole following administration of 15 mg doses of each substance.

'192 patent, col. 5, lines 17-23.

> Higher average AUC results in a more pronounced inhibitory effect on gastric-acid secretion and is expected to result in better overall clinical effect.

> Thus, the alkaline salts of (-)-omeprazole can provide an improved, alternative pharmaceutical formulation and method for the treatment of gastric acid-related diseases."

'192 patent, col. 7, lines 3-16. *See also* '192 patent, col. 2, lines 38-46. Astra also points to the testimony of Dr. Andersson referred to above. The Court finds such evidence clearly supports the construction proposed by Astra and its position that the term "increased" references a comparison to omeprazole, and therefore shall construe "an increased average plasma levels (AUC)" to mean "greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve."

With respect to the terms "per dosage unit" or "per unit dosage," Astra fails to provide adequate support for its proposed construction. Moreover, because the ordinary and customary meaning of these terms would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

4. "less pronounced increase in gastrin levels" in "slow metabolisers"

The first term, "less pronounced increase in gastrin levels" appears in claim 3 and 15. The second, "slow metabolisers," appears in 3, 4, 15 and 16. Astra contends that "less pronounced increase in gastrin levels" should be construed as "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole." Astra further asserts that "slow metabolisers" means "the few individuals among a population that lack one or more drug metabolizing enzymes or express

a mutant form of one or more drug metabolizing enzymes. In humans, the relevant drug metabolizing enzymes, include enzymes of the CYP1, CYP2 and CYP3 families and the 6 isoforms within these families. For purposes of the '192 patent, a "slow metabolizer" is individual which lacks the CYP2C19."

DRL argues that construction of the phrase "less pronounced increase in gastrin levels [in] slow metabolisers" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4- methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl] -1H-benzimidazole that the average increase in gastrin levels for slow metabolizers treated with that compound is less than that for slow metabolizers treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For the same reasons expressed earlier, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

In support of its proposed construction of "less pronounced increase in gastrin levels"

as meaning "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole," Astra points to the prosecution history of the '192 patent, during which, in response to an office action during prosecution of the '502 patent, Astra submitted a response explaining the pronounced effect of administration of the (-)-enantiomer of omeprazole. Pl. Ex. '192-2. It explained that "[i]n addition as can be recognized from the data of Study B in the Declaration of Andersson, the (-)-omeprazole affords a longer time, 53% of the 24 hour period post dose, with gastric pH above 4 in reflux patients compared to 44% for racemic omeprazole (i.e., about two additional hours) which means a more pronounced acid inhibitory effect." Pl. Ex. '192-10 2/12/1997 Amendment and Response at 8. Astra also relies upon the dictionary definition of the term "pronounced," which is defined as "strongly marked." Pl. Ex. '192-11, Merriam-Webster's Dictionary, 10th Ed., 1993 at 934.

The Court finds that the plain language of the claim, as well as the intrinsic and extrinsic evidence relied upon by Astra, supports the conclusion that one skilled in the art would of ordinary skill would understand that the phrase "less pronounced" refers to a comparison to omeprazole. Consequently, the Court shall construe the phrase "less pronounced increase in gastrin levels" consistent with Plaintiff's proposed construction to mean "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole."

Turning to the language "slow metabolisers," the Court finds ample intrinsic evidence supports the construction proposed by Astra. The specification of the '192 patent explains that some individuals "metabolise omeprazole slowly (slow metabolisers) compared to the rest of the population (rapid metabolisers)" and "obtain higher than the average plasma concentrations of the drug. '192 Patent, col. 2, lines 15-35. The specification further explains that "with respect to drug metabolism in man, three families, CYP1, CYP2, and CYP3 or, more specifically, six different CYP isoforms within these families are particularly important." *Id.*, col. 3, lines 16-20. These are relevant to "interindividual variation in rate and extent of metabolism demonstrated for most drugs." *Id.*, col. 3, lines 16-32. Additionally, "at least two of the CYP isoforms, CYP2C19 and CYP2D6, are polymorphically expressed." *Id.*, col. 3, lines 22-24. Slow metabolisers "lack or express a mutated form of the relevant CYP isoform, and consequently metabolise substrates for this isoform slowly." *Id.*, col. 3, lines 25-27.

Furthermore, the declaration of Dr. Andersson, submitted during prosecution of the '504 patent, explains

> It is known that some individuals (about 3% among Caucasians and about 15% among Asians) exhibit higher (5- to 10-fold) than average plasma concentration versus time curves (AUC) of the drug. The metabolic capacity of this minority of individuals, who are classified as slow or poor metabolizers (as opposed to the majority who are classified as rapid/extensive or "normal" metabolizers), is genetically determined. Omeprazole is mainly metabolized by the polymorphically expressed enzyme CYP2C19. It has been found that the reason for slow metabolism is a lack of activity of the main omeprazole-metabolizing enzyme, the cytochrome P450 (CYP) isoform CYP2C19. Thus, while rapid metabolizers express an active CYP2C19, the slow metabolizers do not. This means that the difference in plasma levels of omeprazole between those who express an active form of this liver enzyme

> and those who do not is substantial. This leads to a certain degree of interindividual variation in plasma levels within the total population during treatment with omeprazole. Thus, there is several fold difference in plasma levels between those individuals who express a functional enzyme (rapid metabolizers) and those who do not (slow metabolizers).

Pl. Ex. '192-6, Andersson Declaration, at 5-6. Consequently, the Court shall construe the term "slow metabolisers" to mean "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole."

5. "decreased CYP1A induction"

This term appears in claims 4 and 16. Astra contends that this term should be construed as "a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole." DRL argues that construction of the phrase "decreased CYP1A induction" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5- dimethyl-2 pyridinyl)methyl]sulfinyl]- 1Hbenzimidazole that the average CYP1A induction in slow metabolizers treated with that compound is less than that in slow metabolizers treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For reasons discussed above, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this phrase is appropriate. Because DRL's proposed

construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

Astra asserts that both the claim language and the '192 specification support its proposed construction. The Court agrees that a person skilled in the art reading the plain language of the claim would understand that the term "decreased" referred to a comparison to omeprazole. This is further supported by the specification, which explains that "[t]he use of the (-)-enantiomer of omeprazole would decrease the potential for CYP1A2 induction in slow metabolisers as a result of the lower plasma levels (AUC) of this compound obtained in these individuals. Since the gastrin levels obtained simply are a result of a natural feedback mechanism determined by the degree of inhibition of gastric acid secretion, the use of the (-)-enantiomer of omeprazole may also potentially result in a less pronounced increase in gastrin in slow metabolisers." '192 patent, col. 3, lines 53-61). Therefore, the Court shall construe the term "decreased CYP1A induction" to mean "a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole."

6. "so as to elicit an improved antisecretory effect"

The term "so as to elicit" appears in claims 5 and 6. The term "an improved antisecretory effect" appears in claims 5 and 17. Plaintiff contends that "so as to elicit" should be construed to mean "to bring about." Plaintiff further asserts that "an improved

antisecretory effect" means "an enhanced ability to decrease gastric acid secretion." DRL, on the other hand, argues that construction of the phrase "so as to elicit an improved antisecretory effect" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent antisecretory effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5- methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl] sulfinyl]-1Hbenzimidazole during treatment of gastric acid related diseases, where the improved antisecretory effect is sufficiently better than that of omeprazole such that it would support a claim of superiority that the FDA would allow in advertising and product literature." For reasons discussed above, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of certain terms within this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

First, Plaintiff proposed construction for the term "so as to elicit" is "to bring about." As best as the Court can construe from Astra's papers, Astra relies primarily on the dictionary definition of "elicit," which means "to draw forth or bring out." Miriam Webster's Dictionary, 10th ed., 1993 at 374. However, because there is no ambiguity as to

the meaning of the phrase "so as to elicit" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

Next is the phrase "an improved antisecretory effect," which Astra contends should be construed as "an enhanced ability to decrease gastric acid secretion." With regard to intrinsic evidence, Astra asserts that both the claim language and the '192 specification support its proposed construction. The Court agrees that a person skilled in the art reading the plain language of the claim would understand that the term "improved" referred to a comparison to omeprazole. This is further supported by the specification. For example, the specification discloses that "[i]n rapid metabolisers the mean AUC at steady state ... of the (-)-enantiomer of omeprazole was almost 90% higher than that of omeprazole [which] resulted in a more pronounced gastric acid antisecretory effect for the (-)-enantiomer of omeprazole compared to that of omeprazole." '192 patent, col. 5, lines 17-20. The Court, therefore, shall construe the term "an improved antisecretory effect," consistent with Plaintiff's proposed construction, namely, "an enhanced ability to decrease gastric acid secretion."

7. "an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief"

This phrase appears in claims 6 and 18. Claim 6 states as follows: "The method according to claim 1 or 2 so as to elicit *an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief* during the treatment of gastric related

diseases." '192 patent, col. 7, lines 46-49 (emphasis supplied). Claim 18 states: "The method according to claim 12, wherein the medicament causes *an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief* during the treatment of gastric related diseases." *Id.*, col. 8, line 36-39 (emphasis supplied).

Astra proposes the following constructions of the terms in the disputed phrase: (1) "an improved clinical effect" means "an enhanced ability to mitigate observed symptoms, effects or course of a disease;" (2) "comprising" means "at least the following;" and (3) "accelerated rate of healing and accelerated rate of symptom relief" means "a faster resolution of symptoms or effects of a disease, compared to omeprazole." DRL argues that construction of the phrase "an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief" is not required because it is not a limitation but rather the observed inherent result of the claimed method. Alternatively, DRL proposes the following construction: the observed inherent clinical effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl]-1Hbenzimidazole during treatment of gastric acid related diseases, where the clinical effect is sufficiently better than that of omeprazole such that it would support a claim of superiority that the FDA would allow in advertising and product literature. For reasons discussed above, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of certain terms within this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed phrase simply state the inherent result or

effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

The Court, therefore, examines Astra's proposed construction of the disputed terms. First, Astra contends that properly construed "an improved clinical effect" means "an enhanced ability to mitigate observed symptoms, effects or course of a disease." As it has done with many of the other disputed claim terms, Astra's brief refers the Court to Astra's Exhibit '192-2 for support of its proposed construction. With respect to construction of the term "an improved clinical effect," Exhibit '192-2 refers the Court to the following: "Claim 6 language", "Claim 1," and quotations from three portions of the specification that each contain the word "clinical." Astra, however, does not explain, and the Court does not on its own discern, how the cited material justifies the construction offered by Astra. The Court, therefore, rejects Astra's construction and the term's ordinary and customary meaning to one of ordinary skill in the art shall apply.

Next, Astra seeks construction of the term "comprising." However, Astra's basis for its proposed construction of this term is nowhere addressed in Astra's claim construction papers. Support for Astra's construction is not found in the disputed claims chart, Astra's Exhibit '192-2 or the attachment to the July 2009 Joint Statement. Consequently, the Court rejects Astra's construction of "comprising" and the ordinary and customary meaning of the term as understood by someone of ordinary skill shall apply.

Last is the phrase "accelerated rate of healing and accelerated rate of symptom relief", which Astra asks the Court to construe as "a faster resolution of symptoms or effects of a disease, compared to omeprazole." In support of its proposed construction Astra relies upon the language of the claim itself as well as the specification. In particular, the specification explains that the higher anti-secretory effect of (-)-omeprazole as compared to omeprazole gave rise to the expectation that healing and symptom relief would be faster for patients administered (-)-omeprazole:

> Therefore, the anti-secretory effect, which is directly correlated to the AUC irrespective of compound, was higher for (-)-omeprazole than for omeprazole racemate following administration of identical doses. This is expected to give a clinical advantage for (-)-omeprazole, since the number of patients healed from the acid-related disease is expected to be higher, and healing is also expected to be achieved within a shorter time frame. It might also be expected that a more rapid symptom relief will be obtained.

'192 patent, col. 6, line 61 to col. 7, line 2. Thus, the Court finds that one skilled in the art would understand the term "faster" in the disputed phrase to be referring to a comparison of (-)-omeprazole to omeprazole. Accordingly, the Court shall construe the phrase "accelerated rate of healing and accelerated rate of symptom relief" consistent with Astra's proposed construction, namely, as "a faster resolution of symptoms or effects of a disease, compared to omeprazole."

8. "medicament"

This term appears in claims 12-19. Astra asserts that the Court should construe "medicament" as "medicine." DRL does not propose a construction for this individual term, but rather argues once again that the phrases in which this term appears in claims 12-19 do

not require construction because they are not limitations. Although it rejects DRL's argument, the Court nevertheless shall not construe the term "medicament." Astra provides no basis for its construction, and the Court finds no ambiguity as to the meaning of the term "medicament" to one of ordinary skill. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the term "medicament" as it is used in claims 12-19 the '192 patent. The term's ordinary meaning as understood by those of ordinary skill in the art shall apply.

9. "causes"

This term appears in claims 12-19. Astra asserts that the Court should construe "causes" as "to produce the effect of." DRL does not propose a construction for this term, but rather argues once again that the phrases in which this term appears in claims 12-19 do not require construction because they are not limitations. Although it rejects DRL's argument, the Court shall nevertheless decline to construe the term. Astra provides only a dictionary definition as the basis for its construction. The Court finds no ambiguity as to the meaning of the term "causes," and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the "causes" as it is used in claims 12-19 of the '192 patent. The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.

10. "essentially devoid of its (+)-enantiomeric contaminant"

This term appears in claim 23 which reads: "The method according to claim 1 or 2 wherein the (-)-enantiomer of the proton pump inhibitor is *essentially devoid of its*

(+)-enantiomeric contaminant." '192 patent, col. 8, lines 52-54 (emphasis supplied). Astra asserts that the proper construction of this phrase is "nearly completely lacking an impurity of (+)-omeprazole." Astra further contends that a compound "essentially devoid of its (+)-enantiomeric contaminant" has a "very high optical purity," meaning at least 99.8% e.e., and a higher optical purity than the compound of claim 1. DRL argues that the proper construction of this phrase is "having almost no R-omeprazole [(+)-omeprazole]."

Given the Court's construction of claim 1 and the reasons therefor, the Court shall construe the phrase "essentially devoid of its (+)-enantiomeric contaminant" consistent with Plaintiff's proposed construction.

11. "a method for the treatment of gastric acid related diseases by inhibition of gastric acid secretion"

This term appears in claims 1 and 2. According to Astra, proper construction of this phrase is "a procedure for mitigating a symptom or effect of a condition associated with stomach acid by reducing the amount of acid produced by the stomach." DRL contends that this term need not be construed and the ordinary meaning as understood by those of ordinary skill in the art should apply. However, if construction is required, DRL proposes that the phrase be construed as "a way of treating inflammation the gastrointestinal tract by inhibiting secretion of gastric acid."

The basis for Astra's proposed construction of this term is nowhere addressed in Astra's claim construction papers. The Court, therefore, accepts DRL's argument that this term need not be construed. Because its ordinary and customary meaning would be clear to

one skilled in the art, the Court declines to construe "a method for the treatment of gastric acid related diseases by inhibition of gastric acid secretion" as it is used in claims 1 and 2 of the '192 patent. The terms' ordinary meaning as understood by those of ordinary skill in the art shall apply.

12. "therapeutically effective amount"

This term appears in claims 1, 2 and 12. Astra asserts that this term, properly construed, means "an amount sufficient to reduce the production of acid by the stomach." DRL contends that this term need not be construed and the ordinary meaning as understood by those of ordinary skill in the art should apply. However, if construction is required, DRL proposes that the phrase be construed as "an amount having a therapeutic effect."

Like certain other terms discussed above, Astra's basis for its proposed construction of this term is nowhere addressed in Astra's claim construction papers nor was it addressed at oral argument. The Court, therefore, accepts DRL's argument that this term need not be construed. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe "therapeutically effective amount." The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.

13. "pharmaceutically acceptable salt

This term appears in claims 1, 2, 7-9 and 12. Astra contends that this term should be construed to mean "both acid and alkaline nontoxic ionic compound." DRL contends that this term need not be construed and the ordinary meaning as understood by those of ordinary skill in the art should apply. However, if construction is required, DRL proposes that the

phrase be construed as "a salt that is suitable for use in a pharmaceutical formulation."

Once again, Astra's basis for its proposed construction of this term is nowhere addressed in Astra's claim construction papers. The Court, therefore, accepts DRL's argument that this term need not be construed. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe "pharmaceutically acceptable salt." The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.

III. Conclusion

For the reasons set forth above, the disputed terms at issue will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: May 17, 2010